

### **IN THE CLAIMS**

Please amend claims 1, 17, and 26 and add new claims 36-37 without prejudice to or disclaimer of the subject matter contained therein, as outlined in Appendix A, entitled "Claim Amendments", attached herewith.

### **REMARKS**

Claims 1-37 are currently pending in the present application. Applicants wish to thank the Examiner for the in-person Interview conducted November 21, 2006. As discussed in the Interview, applicants have hereby amended the currently pending claims to further emphasize processes for making compositions, and compositions made by these processes, that have a viscosity lower than the viscosity of an intermediate benzoyl peroxide dispersion used in the process, as agreed to during the Interview. Further, applicants have amended, for example, claim 1 and added, for example, new claim 36, to include stability values demonstrated by the data present in the application specification as suggested by the Examiner during the Interview. Support for these amendments can be found in the original specification as filed at page 8, lines 5-8; page 15, lines 4-9; page 27, line 24 to page 28, line 5; page 28, lines 23-24; page 32, lines 8-18; page 33, lines 16-21; page 34, lines 1-12; and pages 41-47, Tables 1-13. The amendments to the claims do not introduce new matter within the meaning of 35 U.S.C. §132. Additionally, applicants present herein a check for \$300.00 for the addition of two additional total claims and one additional independent claim. Accordingly, entry of the amendments is respectfully requested.

**1. Rejection of Claims 1-11, 14-26, and 30-34 under 35 U.S.C. §102(b)**

The Official Action states that claims 1-11, 14-26, and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Baroody et al. (US 6,117,843).

As the basis of this rejection, the Official Action states:

Claims 1-11, 14-26 and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,117,843 to Broody et al (Broody).

Instant claims are directed to a composition, a method of preparing the composition and a method of treatment, wherein the composition comprises a storage-stable mixture of benzoyl peroxide dispersion, clindamycin and a pharmaceutically acceptable carrier, before mixing and a final pH of 4.5 to 5.0.

Broody discloses a composition comprising clindamycin, benzoyl peroxide and a carrier, for the treatment of acne, which is stable for several months (col. 2, L 3-66). Broody discloses incorporating clindamycin salt that is compatible with the gelling agent and a dispersion of finely divided benzoyl peroxide, wherein the dispersion and clindamycin are combine with a carrier, and further with a gelling agent such as Carbopol (col. 4, L 1-43). Table 1 of Broody shows final composition, which contains the claimed amounts of benzoyl peroxide and clindamycin, and has a pH of 4.5-5.5, which includes the pH of the instant claims. Thus, Broody discloses the composition for the same purpose claimed in the instant application (claims 17-25, in particular claim 22 of the instant application). For claims 2 & 3, Broody discloses applying the composition once or twice daily (col. 7, L 25-35). For claimed stability (claims 7-8), Broody shows that the composition is stable over a long period of time (table 7 and 8). For claims 23-25, Broody does not specify the age group of patients that are treated with the composition. However, the examples show that the composition is highly effective against acne (col. 15-16) and therefore the composition of Broody is effective against all age groups (including those claimed). With respect to the viscosity, Broody discloses that initial viscosity of benzoyl peroxide in the range of 50,000 to 90,000 and a final viscosity in the range of 70,000 to 120,000. For claim 13, instant claims are directed to a final product i.e., composition and broody teaches the viscosity of the composition having a final viscosity that overlaps with the claimed viscosity. Thus, the composition of Broody possesses viscosity in the same range as in the instant composition, and thus, anticipates instant claims.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in

a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). Moreover, the rule of law requires that the Examiner must consider a reference in its entirety in determining the scope and content of the reference. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, (Fed. Cir 1983), *cert. denied*, 469 U.S. 851 (1984). Thus, the Examiner must acknowledge any disclosure in the reference that teaches away from the present invention. Id.

Applicants thank the Examiner for the Interview of November 21, 2006. As discussed during the Interview, applicants respectfully assert that, not only does the Barody et al. reference not teach each and every element of the presently pending claims, but the Barody et al. reference actually teaches away from the presently pending claims.

In particular, the presently pending claims relate to processes for preparing compositions and compositions prepared by these processes that require mixing a benzoyl peroxide dispersion and clindamycin or a pharmaceutically acceptable salt or ester thereof, such that the final composition has a viscosity lower than the viscosity of the benzoyl peroxide dispersion before mixing. All of the presently pending independent claims, namely claims 1, 26, 36, and 37, specifically require the preparation of a final product having a viscosity lower than the viscosity of the benzoyl peroxide dispersion.

In contrast, at col. 5, lines 48-57, Baroody et al. specifically disclose two component kits containing benzoyl peroxide and e.g., clindamycin, wherein “the benzoyl peroxide component itself may be maintained at a relatively low viscosity while the final topical composition (which is at a different pH) will have a relatively higher viscosity. In this way, mixing of the two components to form the topical composition is facilitated (i.e. the lower viscosity of the benzoyl peroxide component makes the combination and mixing with the clindamycin component easier) while the final topical composition can still possess the desired higher viscosity, gel consistency.” Similarly, at col. 6, lines 23-26, Baroody et al. specifically disclose that “a beneficial increase in viscosity can be achieved”.

Accordingly, as discussed with the Examiner during the Interview, not only does the Baroody et al. reference fail to disclose the requirement of the presently pending claims that the final composition has a viscosity lower than the viscosity of the intermediate benzoyl peroxide dispersion, but the Baroody et al. reference teaches the exact opposite, requiring the final composition to have a viscosity higher than the benzoyl peroxide intermediate composition. The Baroody et al. reference, then, does not anticipate the presently pending claims because it 1) fails to disclose each and every element of the presently pending claims as required by *Verdegaal Bros. v. Union Oil Co. of California*; and 2) actually teaches the exact opposite of, and thus teaches away from, the presently pending claims.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of presently pending claims 1-11, 14-26, and 30-34.

## **2. Rejection of Claims 13, 27-29, and 35 under 35 U.S.C. §103(a)**

The Official Action states that claims 13, 27-29, and 35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Broody et al.

As the basis of this rejection, the Official Action states:

Claims 13, 27-29 and 35 are rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,117,843 to Broody et al. (Broody). Broody does not teach the purity of benzoyl peroxide, viscosity of benzoyl peroxide of claim 13, the percentage degradation of clindamycin or the amounts of benzoyl peroxide and clindamycin in the claimed standard deviation. However, Broody also recognize the same factors i.e., pH, viscosity etc., that affect the stability (result-affective variables) of the composition and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ pure active compounds and optimize the general conditions such as viscosity, amounts of active agents with an expectation to achieve a composition that stable for long periods of time because the teachings of Broody are also directed to preparing a storage stable composition comprising benzoyl peroxide and clindamycin and employed for the same purpose similar to the instant invention i.e., treatment of acne or other skin related conditions that need require benzoyl peroxide and clindamycin combination. Where the general conditions of a claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Applicants respectfully traverse the rejection of presently pending claims 13, 27-29, and 35. The reference of record does not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. The Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior

art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants thank the Examiner for the Interview of November 21, 2006. As discussed during the Interview, applicants respectfully assert that, not only does the Barody et al. reference not teach each and every element of the presently pending claims, but the Barody et al. reference actually teaches away from the presently pending claims.

In particular, applicants hereby incorporate by reference in its entirety the discussion in Section 1 above regarding the scope of the presently pending claims, the scope of the Barody et al. reference cited by the Examiner, and the differences between the two. As noted above, the Barody et al. reference does not teach, disclose, or render obvious any of the presently pending claims because it fails to disclose the requirement of the presently pending claims that the final composition has a viscosity lower than the viscosity of the intermediate benzoyl peroxide dispersion, but instead teaches the exact opposite, requiring the final composition to have a viscosity higher than the benzoyl peroxide intermediate composition. Accordingly, the Barody et al. reference does not teach, disclose, or render obvious any of the presently pending claims.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of presently pending claims 13, 27-29, and 35.

### **CONCLUSION**

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the outstanding rejections and allow all pending claims 1-37. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

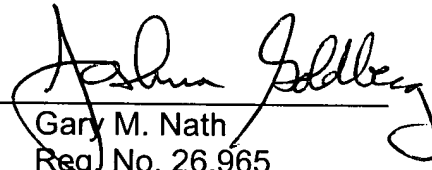
The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

**NATH & ASSOCIATES PLLC**

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